

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service  
Food and Drug Administration**San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700**VIA REGISTERED MAIL**  
**RETURN RECEIPT REQUESTED**

Our Reference: 3004969953

April 13, 2005

Two Feathers, Inc.  
P.O. Box 8033  
Reno, NV 89507  
and  
Robert Roy Two Feathers  
630 West 10<sup>th</sup> Street  
Reno, NV 89503  
and  
Robert Roy  
507D Casazza Drive  
Reno, NV 89502

**WARNING LETTER**

Dear Mr. Two Feathers:

This letter concerns Two Feathers Healing Formula, aka Compound X (hereafter Healing Formula), marketed by your firm on the Internet website [www.healingformula.net](http://www.healingformula.net). According to information on this website, you sell Healing Formula as a treatment and cure for cancer, tumors, venereal diseases, and internal malignancies. Healing Formula can be used topically and also can be ingested, used as an enema, or used as a douche. Ordering instructions, including the price of the drug and shipping information, are provided on the website. Consumers may place an order by calling a toll-free telephone number, or by placing an email order to [Robert@healingformula.net](mailto:Robert@healingformula.net).

The intended uses of the Healing Formula are conveyed on your Internet site. These include statements such as:

- "one eighth of a teaspoon . . . swallowed . . . for internal malignancies of the liver, kidneys, colon, prostate (sic), female sex organs, breasts . . . venereal diseases . . ."

- "When working with any malignancy with a history of more than six months in the body, a problem located in the lower abdominal region or close to the reproductive organs, the salve is used as a douche or an enema . . . ."
- "Testimonials . . . I have taken off two Basal Cell Carcinomas on my face. . . . I had others taken out by surgery many years ago, but were still active, I believe, because the roots were still there. Your formula is drawing all skin cancers, new and old, roots and all . . . ."
- "skin cancer I had on my eye lid . . . The eyelid cancer is gone . . . ."
- "my husband was diagnosed with cancer throughout his body . . . now cancer free . . . ."

Based on the claims cited above, Healing Formula is a "drug" as defined by 21 U.S.C. § 321(g). Moreover, Healing Formula is a "new drug" as defined by 21 U.S.C. § 321(p) because there is no evidence that it is generally recognized as safe and effective for these claimed uses. Under 21 U.S.C. § 355(a), a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. The continued distribution of this product without an approved NDA violates 21 U.S.C. §§ 331(d) and 355.

In addition, Healing Formula is misbranded under 21 U.S.C. § 352(f)(1) because its labeling fails to bear adequate directions for the uses for which it is being offered and it is not exempt from this requirement under 21 CFR section § 201.115.

The violations described above are not intended to be an all-inclusive list of your firm's deficiencies. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You must promptly correct these deviations. Failure to do so may result in regulatory action without further notice. Possible actions include seizure, injunction, and/or prosecution.

Please reply in writing within fifteen days of your receipt of this letter regarding the steps that you have taken to correct the above violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be made.

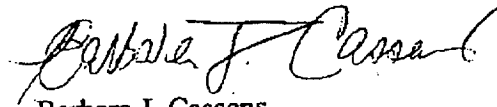
Further, if your firm does not manufacture the product, your reply should also include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Robert Roy Two Feathers  
Two Feathers, Inc.

3

Your response should be directed to Paul A. Peterson, Compliance Officer, Food and Drug Administration, San Francisco District, 1431 Harbor Bay Parkway, CA 94502, phone (510) 337-6856.

Sincerely yours,

A handwritten signature in cursive script, reading "Barbara J. Cassens".

Barbara J. Cassens  
District Director  
San Francisco District